

COPY

## Declaration for Patent Application

Docket Number: 0609.4460002/JAG/HLK

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter that is claimed and for which a patent is sought on the invention entitled An Alpha-2-Macroglobulin Diagnostic Test, the specification of which is attached hereto unless the following box is checked:

- ☒ was filed on September 4, 1998 ;  
as United States Application Number or PCT International Application Number 09/148,503; and  
was amended on \_\_\_\_\_ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information that is material to patentability as defined in 37 C.F.R. § 1.56.

I hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT international application, which designated at least one country other than the United States listed below, and have also identified below any foreign application for patent or inventor's certificate, or PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

Priority Claimed.

\_\_\_\_\_  
(Application No.)

\_\_\_\_\_  
(Country)

\_\_\_\_\_  
(Day/Month/Year Filed)

☐ Yes ☐ No

\_\_\_\_\_  
(Application No.)

\_\_\_\_\_  
(Country)

\_\_\_\_\_  
(Day/Month/Year Filed)

☐ Yes ☐ No

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below.

60/057,655

\_\_\_\_\_  
(Application No.)

September 5, 1997

\_\_\_\_\_  
(Filing Date)

60/093,297

\_\_\_\_\_  
(Application No.)

July 17, 1998

\_\_\_\_\_  
(Filing Date)

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s), or under § 365(c) of any PCT international application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose information that is material to patentability as defined in 37 C.F.R. § 1.56 that became available between the filing date of the prior application and the national or PCT international filing date of this application.

\_\_\_\_\_  
(Application No.)

\_\_\_\_\_  
(Filing Date)

\_\_\_\_\_  
(Status - patented, pending, abandoned)

\_\_\_\_\_  
(Application No.)

\_\_\_\_\_  
(Filing Date)

\_\_\_\_\_  
(Status - patented, pending, abandoned)

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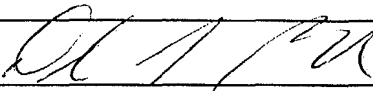
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.  
1100 New York Avenue, N.W.  
Suite 600  
Washington, D.C. 20005-3934

Direct Telephone Calls to:

(202) 371-2600

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

|                                     |  |
|-------------------------------------|--|
| Full name of sole or first inventor | Rudolph E. TANZI   |
| Signature of sole or first inventor | Date   |
| Residence                           | Hull, Massachusetts  |
| Citizenship                         | United States  |
| Post Office Address                 | 3 Ocean View Drive, Hull, Massachusetts 02045              |
|                                     |  |
| Full name of second inventor        | Bradley T. HYMAN   |
| Signature of second inventor        | Date   |
| Residence                           | Swampscott, Massachusetts                                  |
| Citizenship                         | United States  |
| Post Office Address                 | 23 Bayview Avenue, Swampscott, Massachusetts 01907         |
|                                     |  |
| Full name of third inventor         | George W. REBECK   |
| Signature of third inventor         | Date   |
| Residence                           | Somerville, Massachusetts                                  |
| Citizenship                         | United States  |
| Post Office Address                 | 93 Concord Avenue, Apt. 1, Somerville, Massachusetts 02143 |
|                                     |  |

|                              |  |                 |
|------------------------------|--|-----------------|
| Full name of fourth inventor | Deborah L. BLACKER   |                 |
| Signature of fourth inventor |  | Date<br>4/27/99 |
| Residence                    | Newton, Massachusetts  |                 |
| Citizenship                  | United States  |                 |
| Post Office Address          | 31 Brookdale Road, Newton, Massachusetts 02460                                     |                 |
|                              |  |                 |
| Full name of fifth inventor  |  |                 |
| Signature of fifth inventor  |  | Date            |
| Residence                    |  |                 |
| Citizenship                  |  |                 |
| Post Office Address          |  |                 |
|                              |  |                 |

(Supply similar information and signature for subsequent joint inventors, if any)

COPY

### Declaration for Patent Application

Docket Number: 0609.4460002/JAG/HLK

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am the original, first and sole inventor (if only one name is listed below) or an original, first and joint inventor (if plural names are listed below) of the subject matter that is claimed and for which a patent is sought on the invention entitled An Alpha-2-Macroglobulin Diagnostic Test, the specification of which is attached hereto unless the following box is checked:

- ☒ was filed on September 4, 1998 ;  
as United States Application Number or PCT International Application Number 09/148,503; and  
was amended on \_\_\_\_\_ (if applicable).

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by any amendment referred to above.

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I hereby claim foreign priority benefits under 35 U.S.C. § 119(a)-(d) or § 365(b) of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT international application, which designated at least one country other than the United States listed below, and have also identified below any foreign application for patent or inventor's certificate, or PCT international application having a filing date before that of the application on which priority is claimed.

Prior Foreign Application(s)

Priority Claimed

\_\_\_\_\_  
(Application No.)

\_\_\_\_\_  
(Country)

\_\_\_\_\_  
(Day/Month/Year Filed)

☐ Yes ☐ No

\_\_\_\_\_  
(Application No.)

\_\_\_\_\_  
(Country)

\_\_\_\_\_  
(Day/Month/Year Filed)

☐ Yes ☐ No

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below.

60/057,655  
(Application No.)

September 5, 1997  
(Filing Date)

60/093,297  
(Application No.)

July 17, 1998  
(Filing Date)

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s), or under § 365(c) of any PCT international application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose information that is material to patentability as defined in 37 C.F.R. § 1.56 that became available between the filing date of the prior application and the national or PCT international filing date of this application.

\_\_\_\_\_  
(Application No.)

\_\_\_\_\_  
(Filing Date)

\_\_\_\_\_  
(Status - patented, pending, abandoned)

\_\_\_\_\_  
(Application No.)

\_\_\_\_\_  
(Filing Date)

\_\_\_\_\_  
(Status - patented, pending, abandoned)

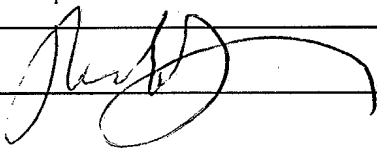
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1100 New York Avenue, N.W.  
Suite 600  
Washington, D.C. 20005-3934

Direct Telephone Calls to:

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I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

|                                       |  |
|---------------------------------------|--|
| Full name of sole or first inventor   | Rudolph E. TANZI   |
| Signature of sole or first inventor ✓ |  5/24/99 Date |
| Residence                             | Hull, Massachusetts  |
| Citizenship                           | United States  |
| Post Office Address                   | 3 Ocean View Drive, Hull, Massachusetts 02045  |
|                                       |  |
| Full name of second inventor          | Bradley T. HYMAN <b>INVENTOR(S) DELETED ON FILING</b>  |
| Signature of second inventor          |  |
| Residence                             | Swampscott, Massachusetts  |
| Citizenship                           | United States  |
| Post Office Address                   | 23 Bayview Avenue, Swampscott, Massachusetts 01907   |
|                                       |  |
| Full name of third inventor           | George W. REBECK <b>INVENTOR(S) DELETED ON FILING</b>  |
| Signature of third inventor           |  |
| Residence                             | Somerville, Massachusetts  |
| Citizenship                           | United States  |
| Post Office Address                   | 93 Concord Avenue, Apt. 1, Somerville, Massachusetts 02143                                     |
|                                       |  |

|                              |  |
|------------------------------|--|
| Full name of fourth inventor | Deborah L. BLACKER                             |
| Signature of fourth inventor | Date   |
| Residence                    | Newton, Massachusetts                          |
| Citizenship                  | United States                                  |
| Post Office Address          | 31 Brookdale Road, Newton, Massachusetts 02460 |
|                              |  |
| Full name of fifth inventor  |  |
| Signature of fifth inventor  | Date   |
| Residence                    |  |
| Citizenship                  |  |
| Post Office Address          |  |
|                              |  |

PAUSERS\HKRAUS\0609446002\PTO\Declaration  
SKGF Rev. 9/2/98 mac

(Supply similar information and signature for subsequent joint inventors, if any)

DO NOT FORWARD  
TO ASSIGNMENT BRANCH  
NOT FOR RECORDATION

ASSIGNMENT

In consideration of the sum of One Dollar (\$1.00) or equivalent and other good and valuable consideration paid to each of the undersigned inventor(s): Deborah L. Blacker. The undersigned inventor(s) hereby sell(s) and assign(s) to The General Hospital Corporation, 55 Fruit Street, Boston, Massachusetts 02114 (the Assignee) his/her entire right, title and interest, including the right to sue for and collect for all past, present and future damages:

check applicable box(es) ☒ for the United States of America (as defined in 35 U.S.C. § 100),  
☒ and throughout the world,

(a) in the inventions known as An Alpha-2-Macroglobulin Diagnostic Test

*29021*  
\_\_\_\_\_ for which  
application(s) for patent in the United States of America has (have) been executed by the  
undersigned inventor(s) on April 27, 1999 (also  
known as United States Application No. 09/148,503, filed September 4, 1998), in any and all  
applications thereon, in any and all Letters Patent(s) therefor, and

(b) in any and all applications that claim the benefit of the patent application(s) listed above in part (a), including continuing applications, reissues, extensions, renewals and reexaminations of the patent application(s) or Letters Patent(s) therefor listed above in part (a), to the full extent of the term or terms for which Letters Patents issue, and

(c) in any and all inventions described in the patent application(s) listed above in part (a), and in any and all forms of intellectual and industrial property protection derivable from such patent application(s), and that are derivable from any and all continuing applications, reissues, extensions, renewals and reexaminations of such patent application(s), including, without limitation, patents, applications, utility models, inventor's certificates, and designs together with the right to file applications therefor; and including the right to claim the same priority rights from any previously filed applications under the International Agreement for the Protection of Industrial Property, or any other international agreement, or the domestic laws of the country in which any such application is filed, as may be applicable; all such rights, title and interest to be held and enjoyed by the above-named Assignee, its successors, legal representatives and assigns to the same extent as all such rights, title and interest would have been held and enjoyed by the Assignor had this assignment and sale not been made.

The undersigned inventor(s) agree(s) to execute all papers necessary in connection with the application(s) and any continuing (continuation, divisional, or continuation-in-part), reissue, reexamination or corresponding application(s) thereof and also to execute separate assignments in connection with such applications as the Assignee may deem necessary or expedient.

The undersigned inventor(s) agree(s) to execute all papers necessary in connection with any interference or patent enforcement action (judicial or otherwise) related to the application(s) or any continuing (continuation, divisional, or continuation-in-part), reissue or reexamination application thereof and to cooperate with the Assignee in every way possible in obtaining evidence and going forward with such interference or patent enforcement action.

The undersigned inventor(s) hereby represents that he/she has full right to convey the entire interest herein assigned, and that he/she has not executed, and will not execute, any agreement in conflict therewith.

The undersigned inventor(s) hereby grant(s) Robert Greene Sterne, Esquire, Registration No. 28,912; Edward J. Kessler, Esquire, Registration No. 25,688; Jorge A. Goldstein, Esquire, Registration No. 29,021; Samuel L. Fox, Esquire, Registration No. 30,353; David K.S. Cornwell, Esquire, Registration No. 31,944; Robert W. Esmond, Esquire, Registration No. 32,893; Tracy-Gene G. Durkin, Esquire, Registration No. 32,831; Michele A.

Cimbala, Esquire, Registration No. 33,851; Michael B. Ray, Esquire, Registration No. 33,997; Robert E. Sokohl, Esquire, Registration No. 36,013; Eric K. Steffe, Esquire, Registration No. 36,688; and Michael Q. Lee, Esquire, Registration No. 35,239, of STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C., 1100 New York Avenue, N.W., Suite 600, Washington, D.C. 20005-3934, power to insert in this assignment any further identification that may be necessary or desirable in order to comply with the rules of the United States Patent and Trademark Office for recordation of this document.

IN WITNESS WHEREOF, executed by the undersigned inventor(s) on the date opposite his/her name(s).

Date: 4/27/99 Signature of Inventor:   
Deborah L. BLACKER

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002533-081004



DO NOT FORWARD  
TO ASSIGNMENT BRANCH  
NOT FOR RECORDATION

## ASSIGNMENT

In consideration of the sum of One Dollar (\$1.00) or equivalent and other good and valuable consideration paid to each of the undersigned inventor(s): Rudolph E. TANZI, Bradley T. HYMAN and George W. REBECK, The undersigned inventor(s) hereby sell(s) and assign(s) to The General Hospital Corporation, 55 Fruit Street, Boston, Massachusetts 02114 (the Assignee) his/her entire right, title and interest, including the right to sue for and collect for all past, present and future damages:

check applicable box(es) ☒ for the United States of America (as defined in 35 U.S.C. § 100),  
☒ and throughout the world,

(a) in the inventions known as An Alpha-2-Macroglobulin Diagnostic Test

\_\_\_\_\_ for which  
application(s) for patent in the United States of America has (have) been executed by the undersigned inventors on \_\_\_\_\_ (also known as United States Application No. 09/148,503, filed September 4, 1998), in any and all applications thereon, in any and all Letters Patent(s) therefor, and

(b) in any and all applications that claim the benefit of the patent application(s) listed above in part (a), including continuing applications, reissues, extensions, renewals and reexaminations of the patent application(s) or Letters Patent(s) therefor listed above in part (a), to the full extent of the term or terms for which Letters Patents issue, and

(c) in any and all inventions described in the patent application(s) listed above in part (a), and in any and all forms of intellectual and industrial property protection derivable from such patent application(s), and that are derivable from any and all continuing applications, reissues, extensions, renewals and reexaminations of such patent application(s), including, without limitation, patents, applications, utility models, inventor's certificates, and designs together with the right to file applications therefor; and including the right to claim the same priority rights from any previously filed applications under the International Agreement for the Protection of Industrial Property, or any other international agreement, or the domestic laws of the country in which any such application is filed, as may be applicable; all such rights, title and interest to be held and enjoyed by the above-named Assignee, its successors, legal representatives and assigns to the same extent as all such rights, title and interest would have been held and enjoyed by the Assignor had this assignment and sale not been made.

The undersigned inventor(s) agree(s) to execute all papers necessary in connection with the application(s) and any continuing (continuation, divisional, or continuation-in-part), reissue, reexamination or corresponding application(s) thereof and also to execute separate assignments in connection with such applications as the Assignee may deem necessary or expedient.

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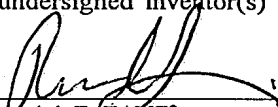
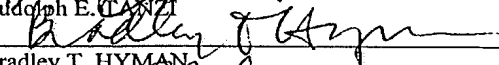
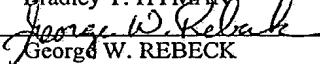
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The undersigned inventor(s) hereby grant(s) Robert Greene Sterne, Esquire, Registration No. 28,912; Edward J. Kessler, Esquire, Registration No. 25,688; Jorge A. Goldstein, Esquire, Registration No. 29,021; Samuel L. Fox, Esquire, Registration No. 30,353; David K.S. Cornwell, Esquire, Registration No. 31,944; Robert W.

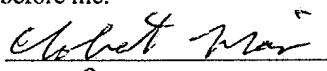
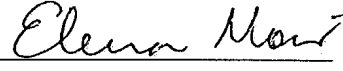
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Esmond, Esquire, Registration No. 32,893; Tracy-Gene G. Durkin, Esquire, Registration No. 32,831; Michele A. Cimbala, Esquire, Registration No. 33,851; Michael B. Ray, Esquire, Registration No. 33,997; Robert E. Sokohl, Esquire, Registration No. 36,013; Eric K. Steffe, Esquire, Registration No. 36,688; and Michael Q. Lee, Esquire, Registration No. 35,239, of STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C., 1100 New York Avenue, N.W., Suite 600, Washington, D.C. 20005-3934, power to insert in this assignment any further identification that may be necessary or desirable in order to comply with the rules of the United States Patent and Trademark Office for recordation of this document.

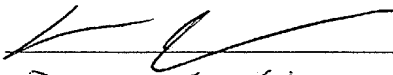
IN WITNESS WHEREOF, executed by the undersigned inventor(s) on the date(s) opposite his/her name(s).

Date: 10/15/98 Signature of Inventor:   
Rudolph E. TANZI  
Date: 10/16/98 Signature of Inventor:   
Bradley T. HYMAN  
Date: 10/16/98 Signature of Inventor:   
George W. REBECK  
Date: \_\_\_\_\_ Signature of Inventor: \_\_\_\_\_

Witnessed before me:

Signature:  Signature:   
Print Name: Robert Moir Print Name: Elena Moir  
Address: 8 Whittier Place Address: 8 Whittier Place # 36, Boston  
#36, Boston

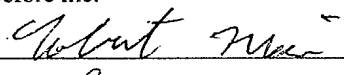
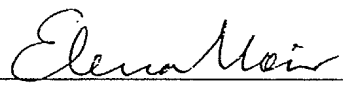
IN WITNESS WHEREOF, executed on behalf of the said ASSIGNEE, The General Hospital Corporation, on the date below:

By:   
David J. Flus  
[Type/Print Name]

Title: \_\_\_\_\_

Date: 10/26/98.

Witnessed before me:

Signature:  Signature:   
Print Name: Robert Moir Print Name: Elena Moir  
Address: 8 Whittier Place Address: 8 Whittier Place # 36, Boston  
#36, Boston

P:\USERS\HKRAUS\0609\446\002\PTO\Assignment

COPY

POWER OF ATTORNEY FROM ASSIGNEE

The General Hospital Corporation, a corporation of Massachusetts, having a principal place of business at 55 Fruit Street, Boston, Massachusetts 02114, is assignee of the entire right, title and interest for the United States of America (as defined in 35 U.S.C. § 100), by reason of Assignments to the Assignee executed on October 15, 1998, October 16, 1998 and April 27, 1999, of an invention known as An Alpha-2-Macroglobulin Diagnostic Test (Attorney Docket No. - 0609.4460002), which is disclosed and claimed in a patent application of the same title by the inventors Rudolph E. Tanzi, Bradley T. Hyman, George W. Rebeck and Deborah L. Blacker (said application filed on September 4, 1998 at the U.S. Patent and Trademark Office, having Application Number 09/148,503).

The Assignee hereby appoints the following U.S. attorneys to prosecute this application and any continuation, divisional, continuation-in-part, or reissue application thereof, and to transact all business in the U.S. Patent and Trademark Office connected therewith: Robert Greene Sterne, Registration No. 28,912; Edward J. Kessler, Registration No. 25,688; Jorge A. Goldstein, Registration No. 29,021; Samuel L. Fox, Registration No. 30,353; David K.S. Cornwell, Registration No. 31,944; Robert W. Esmond, Registration No. 32,893; Tracy-Gene G. Durkin, Registration No. 32,831; Michele A. Cimbala, Registration No. 33,851; Michael B. Ray, Registration No. 33,997; Robert E. Sokohl, Registration No. 36,013; Eric K. Steffe, Registration No. 36,688, Michael Q. Lee, Registration No. 35,239; and Steven R. Ludwig, Registration No. 36,203. The Assignee hereby grants said attorneys the power to insert on this Power of Attorney any further identification that may be necessary or desirable in order to comply with the rules of the U.S. Patent and Trademark Office.

Send correspondence to:

Sterne, Kessler, Goldstein & Fox P.L.L.C.  
1100 New York Avenue, N.W.  
Suite 600  
Washington, D.C. 20005-3934  
U.S.A.

Direct phone calls to 202-371-2600.

FOR: The General Hospital Corporation

SIGNATURE: [Signature]

BY: David J. Glass

TITLE: Associate Director for Patents, Office of Technology Affairs

DATE: June 18, 1999

09525313-081001

## Certificate Under 37 C.F.R. § 3.73(b)

Applicant/Patent Owner: Tanzi et al.

Application No.: 09/148,503

Filed Date: September 4, 1998

Entitled: An Alpha-2-Macroglobulin Diagnostic Test

The General Hospital Corporation

(Name of Assignee)

, a Corporation of Massachusetts

(Type of Assignee, e.g., corporation, partnership, university, government agency, etc.)

states that it is:

1. ☒ the assignee of the entire right, title, and interest, or
2. ☐ an assignee of an undivided part interest

in the patent application identified above by virtue of either:

- A. ☒ An Assignment from the inventor(s) of the patent application/patent identified above. The assignment was recorded in the Patent and Trademark Office at Reel 9598, Frame 0307, or for which a copy thereof is attached.
- ☐ Additional documents in the chain of title are listed on a supplemental sheet.

☒ Copies of assignments or other documents in the chain of title are attached.

[NOTE: A separate copy (i.e., the original assignment document or a true copy of the original document) must be submitted to Assignment Division in accordance with 37 CFR Part 3, if the assignment is to be recorded in the records of the PTO. See MPEP 302-302.8]

The undersigned (whose title is supplied below) is empowered to act on behalf of the assignee.

Date: ☒ June 18, 1999

Name: ☒ DAVID J. GLASS, Ph.D.  
ASSOCIATE DIRECTOR FOR PATENTS  
OFFICE OF TECHNOLOGY AFFAIRS

Title: ☒ \_\_\_\_\_

Signature: ☒ 

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09925313-061001